STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

DIVISION 4, TITLE 27 CALIFORNIA CODE OF REGULATIONS

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

FINAL REGULATORY TEXT

§27000. CHEMICALS REQUIRED BY STATE OR FEDERAL LAW TO HAVE BEEN TESTED FOR POTENTIAL TO CAUSE CANCER OR REPRODUCTIVE TOXICITY, BUT WHICH HAVE NOT BEEN ADEQUATELY TESTED AS REQUIRED.

(a) The Safe Drinking Water and Toxic Enforcement Act of 1986 requires the Governor to publish a list of chemicals formally required by state or federal agencies to have testing for carcinogenicity or reproductive toxicity, but that the state's qualified experts have not found to have been adequately tested as required [Health and Safety Code Section 25249.8(c)].
~~Readers should note a chemical that already has been designated as known to the state to cause cancer or reproductive toxicity is not included in the following listing as requiring additional testing for that particular toxicological endpoint. However, the "data gap" may continue to exist, for purposes of the state or federal agency's requirements. Additional information on the requirements for testing may be obtained from the specific agency identified below.~~

(b) Chemicals required to be tested by the California Department of Pesticide Regulation.

~~The Birth Defect Prevention Act of 1984 (SB 950) mandates that the California Department of Pesticide Regulation (CDPR) review chronic toxicology studies supporting the registration of pesticidal active ingredients. Missing or unacceptable studies are identified as data gaps. The studies are conducted to fulfill generic data requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the United States Environmental Protection Agency (U.S. EPA). The studies are reviewed by CDPR according to guidelines and standards promulgated under FIFRA. Thus, older studies may not meet current guidelines.~~
~~The existence of a data gap for a compound does not indicate a total lack of information on the carcinogenicity or reproductive toxicity of the compound. In some cases, information exists in the open scientific literature, but SB 950 requires specific additional information. A data gap does not necessarily indicate that an oncogenic or reproductive hazard exists. For the purposes of this list, a data gap is still considered to be present until the study is reviewed and found to be acceptable.~~
~~Following is a listing of SB 950 data gaps for oncogenicity, reproduction, and teratology studies for the non-200 pesticidal active ingredients. This list will change as data gaps are filled by additional data or replacement studies.~~

~~For purposes of this section, “onc mouse” means oncogenicity in mice, “onc rat” means oncogenicity in rats, “repro” means reproduction, “tera rat” means teratogenicity in rats, “tera rabbit” means teratogenicity in rabbits.~~

(1) The Birth Defect Prevention Act of 1984 (SB 950) mandates that the California Department of Pesticide Regulation (CDPR) review chronic toxicology studies supporting the registration of pesticidal active ingredients. Missing or unacceptable studies are identified as data gaps.

(2) The studies are conducted to fulfill generic data requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the United States Environmental Protection Agency (U.S. EPA).

(3) The studies are reviewed by CDPR according to guidelines and standards promulgated under FIFRA. Older studies may not meet current guidelines.

(4) The existence of a data gap for a compound does not indicate a total lack of information on the carcinogenicity or reproductive toxicity of the compound. In some cases, information exists in the open scientific literature, but SB 950 requires specific additional information.

(5) A data gap does not necessarily indicate that an oncogenic or reproductive hazard exists. For the purposes of this list, a data gap is still considered to be present until the study is reviewed and found to be acceptable.

(6) Following is a listing of SB 950 data gaps for oncogenicity, reproduction, and teratology studies for pesticidal active ingredients. This list changes as data gaps are filled by additional data or replacement studies.

(7) For purposes of this section, "onc mouse" means oncogenicity in mice, "onc rat" means oncogenicity in rats, "repro" means reproduction, "tera rat" means teratogenicity in rats, "tera rabbit" means teratogenicity in rabbits.

Chemical	*Testing Needed*
Acid Blue 9*	onc rat, onc mouse, repro, tera rat, tera rabbit
Acid Yellow 23*	onc rat, onc mouse, repro, tera rat, tera rabbit
Alkyl-1,3-propylene diamine acetate alkyl derived from coconut oil fatty acids	tera rat, tera rabbit (only one required)
Borax*	onc rat, repro
Bromadiolone*	onc rat, onc mouse, repro, tera rat, tera rabbit

Butoxy polypropylene glycol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Butoxy polypropoxy polyethoxy ethanol – iodine complex*	tera rat
Castor oil*	onc rat, onc mouse, repro, tera rat, tera rabbit
Chlorophacinone*	onc rat, onc mouse, repro
Chromic acid*	onc rat, onc mouse, repro, tera rabbit
Disodium octaborate tetrahydrate	onc rat, repro
Menthol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Meta-cresol*	tera rat, onc rat, onc mouse, repro, tera rabbit
2,2-(Methyl trimethylene dioxy)bis-(4-methyl-1,3,2-dioxaborinane)*	onc rat, onc mouse, repro, tera rabbit
Mineral oil*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum distillates*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum distillates, refined*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum oil, paraffin based*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum oil, unclassified*	onc rat, onc mouse, repro, tera rat, tera rabbit
Propylene oxide*	repro, tera rat, tera rabbit,
Sodium chlorate*	onc rat
Sodium fluoride*	repro, tera rat, tera rabbit
Sodium phenate*	tera rat
Tetraglycine hydroperiodide*	onc rat, onc mouse, repro, tera rat, tera rabbit (only one required)
Triethylene glycol*	onc rat, onc mouse, repro, tera rat, tera rabbit
2,4-Xylenol*	onc rat, onc mouse, repro, tera rat, tera rabbit

* Claims are pending review that data should not be required.

(c) Chemicals required to be tested by the U.S. EPA Office of Pollution Prevention and Toxics

~~Under Section 4(a) of the Toxic Substances Control Act, testing of a chemical is required when that chemical may present an unreasonable risk, or is produced in substantial quantities and enters the environment in substantial quantities, or may have significant or substantial human exposure.~~
~~For purposes of this section, "tera" means teratogenicity, "rtox" means reproductive toxicity, "onc" means oncogenicity.~~

(1) Under 15 U.S.C.A. § 2603(a) of the Toxic Substances Control Act, testing of a chemical is required when that chemical may present an unreasonable risk, or is produced in substantial quantities and enters the environment in substantial quantities, or may have significant or substantial human exposure.

(2) For purposes of this section, "tera" means teratogenicity, "rtox" means reproductive toxicity, "onc" means oncogenicity.

Chemical	*Testing Needed*
Acetaldehyde	rtox
Alkenes, C_{12-24}, chloro	rtox
Benzenediamine, ar,ar-diethyl-ar-methyl-	rtox
Benzenesulfonyl chloride	rtox
1H,3H-Benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone	rtox
C.I. Leuco Sulphur Black 1	rtox
Castor oil, sulfated, sodium salt	rtox
D-gluco-heptonic acid, monosodium salt, (2.xi.)-	rtox
Ethylene dichloride	rtox
2,4-Hexadienoic acid, (E,E)-	rtox
Hydrocarbons, C>4	rtox
Phosphorochloridothioic acid, O,O-diethyl ester	rtox
1,1'-Oxybis[2,chloro-ethane]	rtox

~~NOTE: The testing of the above chemicals is being carried out under "Enforceable Consent Agreements" (or ECAs) under Section 4 of TSCA. In addition, there are a number of ongoing TSCA testing action development activities that may be of interest in the context of Proposition 65. When promulgated, these TSCA Section 4 Test Rules and/or ECAs will require industry to conduct reproductive toxicity, developmental toxicity, and/or cancer studies on a number of 1) hazardous air pollutants (or HAPs), 2) chemicals frequently found at Superfund sites, and 3) U.S. high production volume (or HPV) chemicals. As these, and possibly other, TSCA Section 4 Test Rules/ECAs become effective, this table will be revised to reflect those additional chemical~~

~~substances for which developmental toxicity, reproductive toxicity, and/or oncogenicity testing is currently being required under Section 4 of TSCA.~~

(d) Chemicals required to be tested by the U.S. EPA, Office of Pesticide Programs.

~~The U.S. EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires U.S. EPA to register pesticides based on data adequate to demonstrate that they will not result in unreasonable adverse effects to people or the environment when used in accordance with their U.S. EPA-approved labels.~~
~~In 1988, FIFRA was amended to strengthen U.S. EPA's pesticide regulatory authority and responsibilities to reregister pesticides registered prior to 1984 to ensure they meet today's stringent scientific and regulatory standards. Reregistration requires registrants to develop up-to-date data bases for each pesticide active ingredient. As part of the reregistration process, modifications may be made to registrations, labels or tolerances to ensure they are protective of human health and the environment. Also, reregistration reviews will identify any pesticides where regulatory action may be necessary to deal with unreasonable risks. U.S. EPA has been directed to accelerate the reregistration process so that the entire process is completed by 1997. The 1988 amendments set out a five-phase schedule to accomplish this task with deadlines applying to both pesticide registrants and the U.S. EPA. These amendments are requiring a substantial number of new studies to be conducted and old studies to be reformatted for U.S. EPA review to ensure they are adequate. U.S. EPA may, in the future, request additional data or information to further evaluate any concerns over the safety of pesticide products.~~
~~The chemicals listed below are those for which data are unavailable or inadequate to characterize oncogenicity, teratogenicity, or reproductive effects potential. For purposes of this section, "onc" means oncogenicity, "tera" means teratogenicity, and "repro" means reproductive toxicity.~~

(1) The U.S. EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires U.S. EPA to register pesticides based on data adequate to demonstrate that they will not result in unreasonable adverse effects to people or the environment when used in accordance with their U.S. EPA-approved labels.

(2) The chemicals listed below are those for which data are unavailable or inadequate to characterize oncogenicity, teratogenicity, or reproductive effects potential. For purposes of this section, "onc" means oncogenicity, "tera" means teratogenicity, and "repro" means reproductive toxicity.

Chemical	*Data Requirements*
Benzisothiazolin-3-one	onc

Dithianon	tera
Maneb with ETU	tera
Methyl isothiocyanate	onc, repro, tera
Nicotine and derivatives	repro, tera
Tetramethrin	tera

Revised: ~~February 22, 2017~~ April 1, 2017

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.7, 25249.8(c), 25249.9, 25249.10 and 25249.11. Health and Safety Code.